

K100540

510(k) Summary of Safety and Effectiveness

CAO Group, Inc.
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West Jordan, UT 84084
Tel: 801-256-9282 Fax: 801-256-9287

SEP 23 2010

Robert Larsen,
Preparation Date: August 23, 2010

Device Name:

Trade Name: Ascent F-Coat

Common Name: Cavity Varnish

Product Classification: Varnish, Cavity

Legally Marketed Predicate Devices for Substantial Equivalence:

Vanish Varnish, manufactured by 3M Company (K090519)

DuraShield, manufactured by Dentsply International, Inc. (K082198)

Rationale for Substantial Equivalence:

The aforementioned varnishes share similar indications for use on teeth for alleviating hypersensitivity with the submitted device. The predicate devices and submitted device share similar design features including the incorporation of sodium fluoride and carrier solvents, application time and application methods.

Description of Submitted Device:

The Ascent F-Coat cavity varnish is an ethanol based varnish agent containing 5% sodium fluoride. The material is applied to tooth surfaces where hypersensitivity is a concern. The varnish is applied by a dentist to intact tooth surfaces, or to exposed dentin as a pre-treatment prior to application of temporary restorative materials. The material is a white opaque viscous liquid that is prepackaged in unit-dose applicator ampoules or in preloaded dispensing syringes with disposable brush tips.

Intended Uses of Ascent F-Coat:

The device is intended for the coating of exposed dentin under temporary restorations, and for the treatment of hypersensitive teeth.

Technological Characteristics and Substantial Equivalence:

The Vanish Varnish is a 5% sodium fluoride varnish containing a total 22,600ppm equivalent fluoride ion. The varnish uses an ethanol carrier and makes use of natural resin derivatives as the varnish matrix. The product is intended for use by a dentist for the treatment of hypersensitivity, for use on exposed dentin, and under temporary dental restorations. The material is packaged in unit-dose blister packs and is applied by a disposable brush.

The Durashield Varnish is a 5% sodium fluoride varnish containing a total 22,600ppm equivalent fluoride ion. The varnish uses an ethanol carrier and makes use of natural resin derivatives as the varnish matrix. The product is intended for use by a dentist for the relief of hypersensitivity where exposed dentin or cement, exist. The material is packaged in unit-dose blister packs and is applied by a disposable brush.

Conformity to Standards:

The Ascent F-Coat cavity varnish was evaluated in terms of the recognized standard ISO 7405:2008 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry.

Performance Data

Laboratory testing demonstrates that the subject device contains fluoride ion at the labeled concentration of 5% or 22,600ppm and is at least equivalent to the predicate devices which share similar labeled fluoride content.

Laboratory testing demonstrates that the subject device provides adhesion to the tooth surface at least equal to that of the predicate devices with an average lateral shear adhesion force of 77kPa.

Photomicrographs of the subject device reveal that it is capable of penetrating exposed dentin tubules to a minimum of 3-5 microns.

Laboratory dye penetration tests demonstrate that the subject device is substantially equivalent to the predicate devices in preventing the ingress of fluids into the exposed dentin tubules.

Conclusion

The Ascent F-Coat cavity varnish is substantially equivalent to the listed cavity varnishes without raising any issues of safety or effectiveness. This device shares similar intended uses, and similar functional and performance characteristics. The device is designed to comply with relevant federal and international safety and performance standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert Larsen
Regulatory Affairs Manager
CAO Group, Incorporated
4628 West Skyhawk Drive
West Jordan, Utah 84084

SEP 23 2010

Re: K100540

Trade/Device Name: Ascent F-Coat
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: August 30, 2010
Received: September 3, 2010

Dear Mr. Larsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100540

Indications for Use

SEP 23 2010

510(k) Number (if known): K10 0540

Device Name: Ascent F-Coat

Indications For Use:

Ascent F-Coat is indicated for the coating of exposed dentin under temporary restorations, and for the treatment of hypersensitive teeth.

Prescription Use X AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Burns

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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